

REMARKS

Claims 1-10 are pending, of which claim 10 is withdrawn from consideration. Claims 1-9 are rejected. By this response, Applicants amend claims 1-9 to correct minor errors relating to formalities. Applicants add new claims 11-14. Newly added claims 11-13 are supported, for example, by original claims 2-3, respectively. Newly added claim 14 is supported, for example, by the SUMMARY OF THE INVENTION section of the originally filed specification. As such, no matter has been added. Applicants respectfully request reconsideration of this application.

Specification

Applicants amend the 4th paragraph of page 6 of the specification to change "non-water additives" to "non-soluble additives," as recommended by the Examiner.

Claim Objections

Applicants amend claims 2-9 to add a space between "claim" and "1," as recommended by the Examiner.

Applicants also amend claim 5 to change "a flavoring agent" to "the flavor agent," as recommended by the Examiner.

Claim Rejections - 35 U.S.C. § 112

Claims 4, 5 and 9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants amend claim 4 to change "there may be" to "comprising" and amend claim 5 to change "may be" to "is." Applicants also amend claim 9 to add an "and" between the limitations of "a plasticizer" and "non-soluble agents" and to change "such as" to "selected from a group consisting of." Thus, the rejections of claims 4, 5 and 9 under 35 U.S.C. § 112, second paragraph, have been overcome and should be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by *Tsau et al.* (US 4,971,791). Applicants respectfully traverse this rejection. "A claim is

anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *Tsau* at least fails to teach or suggest the feature of "without a sweetening agent and capable of masking the unpleasant taste" recited in claim 1.

Tsau relates to drug-polymer matrix compositions that include an active ingredient having an amine or amido group and a pharmaceutically acceptable co-polymer having a plurality of carboxylic acid ester groups (see, e.g., *Tsau* at Abstract). To provide a bitterless tablet, the drug-polymer matrix composition disclosed in every example of *Tsau* incorporates a small amount of sweetener (Id. at column 4, line 49 – column 6, line 21). For instance, sorbitol and mannitol (both are sugar alcohols) are used in Example 1; mannitol and sugar are used in Example 2; sugar is used in Example 3; sugar and corn syrup solids are used in Example 4; sugar and sorbitol are used in Example 5; and sugar and mannitol are used in Example 6.

The present application describes a ready mix dry blend composition for preparation of a film coating suspension that can be used for coating of tablets containing unpleasant tasting active ingredients such as albendazole, multivitamins and nutritional supplements. The ready mix composition includes a polymer or a mixture of polymers and a flavoring agent that can be reconstituted in water or organic solvents to provide a flavored film-coating system for application on tablets. The dry mix composition has no sweetening agent since the flavoring agent, in addition to masking the odor, also masks the taste, and as such no extra sweetening agent is needed in the dry mix composition for taste masking. This feature is advantageous, especially for diabetic population who prefer to avoid sweetening agents in any form, and such feature is specifically recited in claim 1: "A ready mix flavored composition for film coating of pharmaceutical oral solid dosage form comprising a polymer and a flavoring agent, but *without a sweetening agent and capable of masking the unpleasant taste* of a solid core." (Emphasis added.) And Applicants note that, based on the teachings of *Tsau*'s examples, one skilled in the art would have no reason to modify *Tsau*'s compositions to remove the sweetener(s) used from these compositions, because doing so would lead to compositions that have bitter tastes, which is directly contrary to the intended purpose of *Tsau* for making "taste

masking compositions." Accordingly, Applicants respectfully submit that claim 1 is patentable over *Tsau* and the rejection of claim 1 under 35 U.S.C. § 102(b) should be withdrawn.

Claim 1-7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Sue* et al. (US 2002/0132006). Applicants respectfully traverse this rejection, because similar to *Tsau*, *Sue* at least fails to teach or suggest the feature of "without a sweetening agent and capable of masking the unpleasant taste" recited in claim 1.

Sue relates to a coating for masking or reducing the detectable presence of certain characteristic odor(s) or taste(s) of pharmaceutical preparations (see, e.g., *Sue* at Abstract). The coating can include one to three coating compartments (Id.). The first coating compartment has a hydroxyalkyl cellulose and an anti-tackiness agent; the second coating compartment has a sugar and an anti-tackiness agent; and the third coating compartment has a methacrylate copolymer, a hydroxyalkyl cellulose and an anti-tackiness agent. The use of sugar in the second coating compartment is to increase the palatability of the pharmaceutical preparations thereby masking the odor or taste of the preparations (Id. at paragraph [0028]). As such, *Sue* employs a sugar coating to reduce odor or taste of pharmaceutical preparations, as the first and third coating compartments have no flavorants or sweeteners for masking of odor or taste in the preparations. In contrast, claim 1 is directed to a ready mix composition where no sweetening agents are used to mask odor or unpleasant taste of medicines. The flavoring agent used in the ready mix composition can mask both odor and taste of pharmaceuticals. Therefore, claim 1 is patentable over *Sue* and so are claims 2-7 because these claims depend from claim 1.

Claim Rejections - 35 U.S.C. § 103

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Sue*. As discussed above, claim 1 is patentable over *Sue*. Since claim 9 depends from claim 1, claim 9 is also patentable over *Sue*.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Sue* in view of *McCabe* et al. (US 5,098,715). As discussed above, claim 1 is patentable over *Sue*. *McCabe* is cited with respect to the features of claim 8 and does not cure the

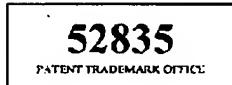
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deficiencies of *Sue* in failing to teach or suggest an odor masking coating that has no sugar (see, e.g., *McCabe* at Abstract, which discloses a flavored coating for application to pharmaceutical tablets that uses a sweetening agent as one of its components). Since claim 8 depends from claim 1, claim 8 is patentable over *Sue* in view of *McCabe*.

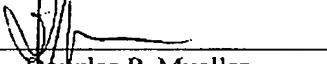
In view of the above amendments and remarks, Applicants respectfully request favorable reconsideration of this application in the form of a Notice of Allowance. If any questions arise regarding this communication, the Examiner is invited to contact Applicants' representative listed below.

Respectfully submitted,



Dated: March 9, 2010

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